Claims

We claim:

1. A method to determine the presence or absence of Streptococcus Group A antigen in a sample, comprising the following steps:

(a) extracting the antigen from said sample in an assay chamber with two or less extraction reagents, wherein said two reagents may be added to said assay chamber in no particular sequence;

(b) introducing a lateral flow immunochromatographic assay device into said extraction reagents containing said extracted antigen without further addition of reagents or manipulation of said sample;

(c) forming an antigen-indicator labeling reagent complex; and

(d) determining the presence or absence of said antigen in the sample by the presence or absence of a signal formed by the binding of said antigen-indicator labeling reagent complex to an indicator capture reagent specific for said antigen-indicator labeling reagent

complex.

2. The method of claim 1 further comprising the step of:

(a) determining the presence of a positive control signal.

3. The method of claim 1 wherein said sample is a throat swab and said extracting further comprises vigorously mixing said throat swab in said extraction reagents for at least 10 seconds.

4. The method of claim 1 wherein said extraction reagents further comprise 0.2-5 M sodium nitrite and 0.02-2 M acetic acid.

5. The method of claim 4 wherein the sodium nitrite solution has a concentration of 2M and the **acetic acid solution has a concentration of 0.3 M,** wherein the 0.3 M acetic acid solution is added to the solution of 2M sodium nitrite, and wherein the color of

the liquid changes from pink to light yellow as said 0.3 M acetic acid solution is added to said 2M sodium nitrite solution.

6. The method of claim 1 wherein said lateral flow immunochromatographic assay device having a sample receiving region containing neutralizing buffer.

7. The method of claim 1 wherein said lateral flow immunochromatographic assay device further comprises a test strip without a plastic housing.

8. The method of claim 1 wherein said lateral flow immunochromatographic assay device further comprises a test strip with a plastic housing.